FEB 2 7 2014

510(k) Summary

Submitter's Name:	Convergent Life Sciences, Inc.
Submitter's Address:	2377 Gold Meadow Way, Suite 160, Gold River, CA 95670
Submitter's Telephone:	916-526-2775
Contact Name:	Dinesh Kumar
Date Summary was Prepared:	11/18/2013
Trade or Proprietary Name:	target3D Fusion
Common or Usual Name:	target3D Fusion
Classification Name:	System, Image Processing, Radiological Picture Archiving and Communications, 21CFR 892.2050
Device Class:	II
Product Code:	LLZ

Predicate Devices:

Device Name	510(k) Number
Multi-Modality Image Fusion	K120187
UROSTATION-3D Prostate Suite	K131448
Syntegra	K041182

Intended Use

target3D Fusion is a software application intended to be used by physicians in a clinic or hospital for visualization in 2D and 3D, registration, and fusion of Ultrasound (US), Magnetic Resonance (MR) and Computed Tomography (CT) images of the prostate. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ and regions of interest delineation, landmark selection, measurements, patient database management, and data reporting.

Description of the Device and Summary of the Technological Characteristics

target3D Fusion is a software application, which allows a physician to segment the prostate gland, and identify and label various structures including regions of interest (ROIs) on a pre-procedural DICOM image. The software further allows a physician to fuse the prepared pre-procedural DICOM image files with one or more intra-procedure live DICOM image files to guide the procedure.

The software can delineate the gland boundary as well the boundaries of any other anatomical landmarks on a pre-procedure DICOM image. The structures including regions of interest are identified using visualization, and stored as standard surface format meshes. Each such structure is labeled uniquely.

target3D Fusion provides a physician with image fusion such that the information from a pre-procedure or planning imaging modality such as MR or CT is mapped to the frame of

reference of the intra-procedure or live imaging modality such as ultrasound for real-time guidance while taking advantage of diagnostic capabilities of the pre-procedural planning image. The mapped information contains at least one structural image, and the target area to be treated. The pre-procedure image is registered with the intra-procedure image using a combination of rigid, affine and non-rigid elastic registration. The registration provides a correspondence or a deformation map, which is used to map planning information from the frame of reference of the planning image to an intra-procedure image.

Substantial Equivalence

target3D Fusion product's technological features are substantially equivalent to its predicate devices. Table 5.1 shows the comprehensive comparison of the features and technological characteristics of target3D Fusion with the predicates. The table shows that all of them:

- are PC based software applications,
- run on Windows operating system,
- provide 2D and 3D medical image acquisition and visualization,
- fuse (co-register) pre-procedure medical images in DICOM formats with intra-procedure medical images,
- provide data communication between imaging modalities,
- provide surface and volume rendering,
- provide multi-planar reformatting,
- allow for organ and regions of interest delineation/segmentation,
- include image enhancements such as zoom controls, and
- incorporate patient database management.

target3D Fusion differs in the following feature from its predicate devices. However, this does not cause any safety or effectiveness concerns:

- target3D Fusion uses a patented co-registration/fusion algorithm, which uses a combination of rigid, affine and non-rigid (elastic) registration.

Table 5.1: Substantial Equivalence of target3D Fusion to its Predicates

Product	target3D Fusion	Multi-Modality Image Fusion	UROSTATION-3D Prostate Suite	Syntegra
Manufacturer	**Convergent Life Sciences**	**Eigen**	**Koelis**	**ADAC Laboratories**
510(k) Number	**pending**	**K120187**	**K131448**	**K041182**
Intended Use	target3D Fusion is a software application intended to be used by physicians in a clinic or hospital for visualization in 2D and 3D, registration, and fusion of Ultrasound (US), Magnetic Resonance (MR) and Computed Tomography (CT) images of the prostate. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ and regions of interest delineation, landmark selection, measurements, patient database management, and data reporting.	Multi-Modality Image Fusion is a software application used by physicians in the clinic or hospital for 2-D and 3-D visualization, multi-modality image registration, and fusion of medical images. Additional software features include database management, communication, surface rendering, segmentation, ROI delineation, measurements, and reporting.	UROSTATION - 3D PROSTATE SUITE With MRI/3DTRUS fusion option and with Second Look 3D)TRUS fusion option is intended to be used by physicians in the clinic or hospital for 2D and 3D) visualization of the prostate gland and for the 3D) transrectal ultrasound based fusion of multiple imaging modalities (ultrasound, MRZI) in order to map such prostate gland. Additional software features include patient data management, multimodal data communication, multiplanar reconstruction, surface and volume rendering, organ delineation, region of interest delineation, 3D3 image registration and data reporting.	Syntegra is a software application for multi- modality image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals.
Product Type	Software	Software	Software	Software
Software Platform	PC running Windows OS	PC running Windows OS	PC running Windows OS	PC running Windows OS
Product Usage	Clinic or hospital	Clinic or hospital	Clinic or hospital	Clinic or hospital

	setting	setting	setting	setting
Product	**target3D Fusion**	**Multi-Modality Image Fusion**	**UROSTATION-3D Prostate Suite**	**Syntegra**
Manufacturer	**Convergent Life Sciences**	**Eigen**	**Koelis**	**ADAC Laboratories**
510(k) Number	**pending**	**K120187**	**K131448**	**K041182**
Visualization of Images	2D and 3D	2D and 3D	2D and 3D	2D and 3D
Image Fusion/Registration	Multiple modality image fusion	Multiple modality image fusion	Multiple modality image fusion	Multiple modality image fusion
Display of Image Fusion	Fused overlay of images from different modalities	Fused overlay of images from different modalities	Fused overlay of images from different modalities	Fused overlay of images from different modalities
Data Communication between Imaging Modalities	Yes	Yes	Yes	Yes
Surface Rendering	Yes	Yes	Yes	Yes
Volume Rendering	Yes	Yes	Yes	Yes
Multi-planar reformatting	Yes	Yes	Yes	Yes
Gland Segmentation	Yes	Yes	Yes	Yes
Regions of Interest Segmentation (Delineation)	Yes	Yes	Yes	Yes
Configurable Image Layouts	Yes	Yes	Yes	Yes
Image Enhancements	Yes	Yes	Yes	Yes

Summary of Testing and Performance Data

The software was tested against the engineering specifications and additional requirements arising from risk management activities. In addition, the software was rigorously tested and debugged as part of product development lifecycle.

The following bench tests were conducted to meet the product requirements and customer expectations:

- **Segmentation Accuracy**: Performance tests for segmentation compared segmentation algorithms in target3D Fusion with ground truth data. Average absolute volume difference errors were found to be 2.8525%.

- **Affine Registration Accuracy:** Affine registration tests were performed to recover synthetic deformations between surfaces. The errors measured as the overlap between objects being registered were found to be under 0.0001 mm.

- **Overall Registration Accuracy:** Registration errors for the entire system that included manual, affine and non-rigid registration were measured by registering multimodality images of phantoms containing beads used as landmarks for computing target registration error. Target registration error measured as the average distance between beads across datasets was found to be 1.7093 mm with a standard deviation of 0.4008 mm.

Conclusion

Substantial equivalence comparison including intended use, function, specifications and technological characteristics of target3D Fusion with the predicate devices demonstrates that target3D Fusion is substantially equivalent to the listed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2014

Convergent Life Sciences, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1934 25th Street NW
BUFFALO MN 55313

Re: K140033
Trade/Device Name: target3D Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 11, 2014
Received: February 12, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

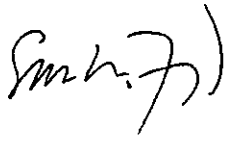
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Pending K140033

Device Name

target3D Fusion

Indications for Use *(Describe)*

target3D Fusion is a software application intended to be used by physicians in a clinic or hospital for visualization in 2D and 3D, registration, and fusion of Ultrasound (US), Magnetic Resonance (MR) and Computed Tomography (CT) images of the prostate. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ and regions of interest delineation, landmark selection, measurements, patient database management, and data reporting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*